



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Chu et al.

Appl. No. 09/438,365

Filed: November 12, 1999

For: New Transfection Reagents

Art Unit:

To be assigned

Examiner:

To be assigned

Atty. Docket: 0942.4650001/RWE/THN

Information Disclosure Statement

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each of these documents is provided.

The Examiner's attention is directed to co-pending U.S. Patent Application Nos. 08/450,555 filed May 25, 1995 and 09/039,780 filed March 16, 1998, which are directed to related technical subject matter. The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to these applications now or upon issuance of present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following concise explanation of the relevance of the non-English language document, Document No. AL1, cited on Form PTO-1449.

Document No. AL1, European Patent No. EP 0 394 111 B1, is in French. It is believed to disclose lipopolyamines, which are especially useful as vectors for the transfection of eukaryotic

cells, their salts, their preparation and their use. Document No. AE1, U.S. Patent No. 5,171,678, is believed to be an English language equivalent of Document No. Al1.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date but before the mailing date of a first Office Action on the merits.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this pleading is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Robert W. Esmond Attorney for Applicants

Registration No. 32,893

Date: March 9, 2000

1100 New York Avenue, N.W. Suite 600 Washington, D.C. 20005-3934 (202) 371-2600

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

Page 1 of 5

APPLICATION NO. 09/438,365 ATTY. DOCKET NO. 0942.4650001

APPLICANT Chu et al.

ETLING DATE

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					FILING DATE November 12, 1999		GROUP To be	assigned	
				U.S	. PATENT DOCUMENTS				
EXAMINER		İ					400	CUD CLASS	
INITIAL			MENT NUMBER	DATE	NAME		LASS 60	SUB-CLASS 584	FILING DATE
	AA1		5,314	11/23/1954	Kosmin, M.		60	47	08/25/1951 05/05/1955
•	AB1		1,461	08/25/1959	Auerbach et al.				
	AC1	3,15	2,188	10/06/1964	Kirkpatrick, W.H.		60	240.2	11/15/1960
	AD1	4,89	7,355	01/30/1990	Eppstein et al.		35	 	
	AE1	5,17	1,678	12/15/1992	Behr et al.		35	172.3	04/17/1990
	AF1	5,20	8,036	05/04/1993	Eppstein et al.		24	450	11/16/1990
	AG1	5,27	9,833	01/18/1994	Rose, J.K.		24	450	04/04/1990
	AH1	-5,28	3,185	02/01/1994	Epand et al.		35	172.3	08/28/1991
	AI1	5,33	4,761	08/02/1994	Gebeyehu et al.	5	64	197	08/28/1992
	AJ1	5,45	5,335	10/03/1995	Kahne et al.	5	36	5	04/08/1994
	AK1		9,127	10/17/1995	Felgner et al.	5	14	7	09/16/1993
				FORE	IGN PATENT DOCUMENTS				
EXAMINER INITIAL		DOCU	MENT NUMBER	DATE	COUNTRY		LASS	SUB-CLASS	TRANSLATION
	AL1	EP 0	394 111 B1	06/04/1997	Europe				Yes No
	AM1	WO 9	04/27435 A1	12/08/1994	WIPO			-	Yes No Yes
	AN								No
	AO								Yes No
	AP								Yes No
		 _	OTHER	(Including Author	or, Title, Date, Pertinent	Pages, et	c.)		
	AR	1	Bangham, A. J. Mol. Bio	D. et al., "Dif 11. 13:238-252 (ffusion of Univalent Ions a	cross the	Lamellae	of Swollen	Phospholipids,"
	Ás'	1	Behr, JP. et al., "Efficient gene transfer into mammalian primary endocrine cells with lipopolyamine-coated DNA," <i>Proc. Natl. Acad. Sci. USA 86</i> :6982-6986 (September 1989).						
	AT	1	Felgner, P	.L. et al., "Li _l " <i>Pro</i> c. Natl. Ad	pofection: A highly efficie cad. Sci. USA 84:7413-7417	ent, lipid (November	-mediated 1987).	d DNA-transfo	ection
EXAMINER						DA	ATE CONSI	DERED	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant. :\USERS\AHYC\094Z\4650001\1449.wpd



Page 2 of 5

ATTY. DOCKET NO. APPLICATION NO. 09/438,365 0942.4650001 FORM PTO-1449 APPLICANT Chu et al. INFORMATION DISCLOSURE STATEMENT GROUP FILING DATE November 12, 1999 To be assigned U.S. PATENT DOCUMENTS **EXAMINER** CLASS SUB-CLASS DOCUMENT NUMBER DATE NAME FILING DATE INITIAL 424 450 08/13/1996 Eppstein et al. 04/03/1995 AA2 5.545.412 564 293 Eppstein et al. 04/03/1995 08/27/1996 AB2 5,550,289 5.14 44 01/26/1995 Felgner *et al*. 12/31/1996 AC2 5,589,466 78.08 424 11/07/1996 AD2 5,667,774 09/16/1997 Figuly, G.D. 514 642 12/20/1993 Haces et al. 10/07/1997 AE2 5,674,908 514 44 01/26/1994 Felgner *et al*. AF2 5,703,055 12/30/1997 01/06/1998 Bally et al. 435 320.1 06/07/1995 AG2 5,705,385 514 10/20/1995 44 Harris et al. AH2 5,719,131 02/17/1998 Hawley-Nelson et al. 320.1 06/04/1996 435 04/07/1998 AI2 5,736,392 514 2 05/16/1995 Ansell et al. 05/19/1998 AJ2 5,753,613 514 44 02/01/1996 07/21/1998 Lee et al. 5,783,565 AK2 FOREIGN PATENT DOCUMENTS FXAMINER SUB-CLASS TRANSLATION COUNTRY CLASS DOCUMENT NUMBER DATE INITIAL Yes No ΑL Yes No AM Yes No AN Yes No ΑO Yes No OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Fukunaga, M. et al., "Liposome Entrapment Enhances the Hypocalcemic Action of Parenterally AR Administered Calcitonin," Endocrinol. 115:757-761 (1984). Gao, X. and Huang, L., "A Novel Cationic Liposome Reagent for Efficient Transfection of Mammalian Cells," Biochem. Biophys. Res. Comm. 179:280-285 (August 1991). AS : 2 Hart, S.L. et al., "Lipid-Mediated Enhancement of Transfection by a Nonviral Integrin-Targeting AT 2 Vector," Hum. Gene Ther. 9:575-585 (March 1998). DATE CONSIDERED EXAMINER EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through

citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



FORM PTO-1449

	INCORMATIO	מא מופני	LOSURE STATE	MENT	Chu et al.					
	INFORMATIO	JN DISC.	<u> </u>		FILING DATE November 12, 1999		GROUP To be a	assigned		
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EXAMINER			ICUT NUMBER	DATE	NAME	CL/	ASS	SUB-CLASS	FILING DATE	
INITIAL			MENT NUMBER	07/21/1998	Mislick, K.A.	514		44	05/10/1996	
	AA3	5,783			Ansell et al.	424		450	09/29/1995	
<u> </u>	AB3	5,785		07/28/1998	Gao et al.	424		450	01/23/1995	
	AC3	5,795		08/18/1998	Unger et al.	424		1.21	02/21/1995	
	AD3	5,830		11/03/1998	Gorman et al.	514		44	06/07/1995	
	AE3	5,830		11/03/1998	Haces et al.	514		42	01/13/1997	
	AF3	5,834		11/10/1998	McDonald et al.	424		450	03/12/1997	
	AG3	5,837		11/17/1998	Lee et al.	514		44	10/20/1995	-
	AH3	5,840		11/24/1998		424		450	08/05/1994	
	A13	5,908		06/01/1999	Thierry, A.	514		44	06/03/1996	
	AJ3	5,935		08/10/1999	Fasbender et al.	55:		540	05/06/1997	
	AK3	5,948	3,925	09/07/1999	Keynes et al.			1 240	03/00/17.	
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٠.	AR	3			on of Multivesicular Lipo			phys. Acta i	728:339-348	
	AS.	3	Mayer, L.D. et al., "Vesicles of variable sizes produced by a rapid extrusion procedure," Biochim. Biophys. Acta 858:161-168 (1986).							
	AT	3	Mayhew, E. Biophys. A	. et al., "Charac cta 775:169-174	cterization of Liposomes (1984).	Prepared Usir	ng a Mic	roemulsifie	r ," Biochim.	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



Page 4 of 5

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 0942.4650001	APPLICATION NO. 09/438,365	
APPLICANT Chu et al.		
FILING DATE	GROUP To be assigned	

NITIAL		November 12, 1999 To be assigned							
NATIAL DOCUMENT NUMBER DATE NAME Substitution by Extrusion Through					U.	S. PATENT DOCUMENTS			
AA4			DOCUME	NT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
A84 5,962,533 10/05/1999 Bergeron, Jr., R.J. 514 674 02/06/1996 AC		AA4	 		09/07/1999	Scheule et al.	514	44	07/12/1996
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		AR	4	Olson, F. Polycarbon	et al., "Prepar ate Membranes,"	ration of Liposomes of Defi Biochim. Biophys. Acta 55.	ned Size Distrib 7:9-23 (1979).	• •	
AS 4 Rosenthal, A.F. and Geyer, R.P., "A Synthetic Inhibitor of Venom Lecithinase A," J. Biol. Characteristics of Venom Lecithinase A," J. Biol. Characteristics (August 1960).		ÁS.	4	Rosenthal, A.F. and Geyer, R.P., "A Synthetic Inhibitor of Venom Lecithinase A," <i>J. Biol. Chem.</i> 235:2202-2206 (August 1960).					
Szoka Jr., F. and Papahadjopoulos, D., "Procedure for preparation of liposomes with large internal aqueous space and high capture by reverse-phase evaporation," <i>Proc. Natl. Acad. Sci 75</i> :4194-4198 (1978).		AT	4	linternal a	aqueous space a	djopoulos, D., "Procedure nd high capture by reverse	for preparation -phase evaporati	of liposomes wi on," <i>Proc. Natl</i>	th large . Acad. Sci. USA
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



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PRAUE TRAUE	MARK			ATTY. DOCKET NO. 0942.4650001	APPLIC 09/438	ATION NO.	Page 5 of 5		
	INFORMATI	FORM PTO-1449 ON DISCLOSURE STATE	EMENT	APPLICANT Chu et al.	APPLICANT				
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION		
	AL					٠.	Yes No		
	AM						Yes No		
	AN						Yes No		
	AO						Yes No		
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	1	OTHER	(Including	Author, Title, Date, Pertinent P	ages, etc.)				

Zhou, X. et al., "Lipophilic polylysines mediate efficient DNA transfection in mammalian cells," Biochim. Biophys. Acta 1065:8-14 (1991). <u>5</u> AR Life Technologies Inc. catalogue, Spectrum, pp. 1-8 (September 1999). <u>5</u> AS: ΑT DATE CONSIDERED EXAMINER

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)

Attorney Docket No.: 61-03

Application No.

: 09/438,3659

Applicant:

: Chu et al.

Filed:

: November 12, 1999

Title:

: New Transfection Reagents

I hereby certify that the following correspondence, along with any other document referred to as being attached or enclosed,:

- 1. Resubmission of Copies of References Previously Submitted in IDS filed March 9, 2000 1 page
- 2. Copy of transmittal letter for previously submitted IDS 2 pages
- 3. Copy of previously submitted Information Disclosure Statement 3 pages
- 4. Copy of previously submitted 1449 5 pages
- 5. Copy of returned post card 1 page
- 6. 16 references
- 7. Certificate of mailing 1 page
- 8. Return Postcard

Is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to:

Commissioner for Patents, PO Box 1450 Alexandria, VA 22313-1450

On May 24, 2005

(Typed or Printed Name of Person Mailing Correspondence)

(Signature of Person Mailing Correspondence)

EV 663 224 876 US

("Express Mail" Mailing Label Number)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.

: 09/438,365

Confirmation No.: 9217

Applicant:

: Chu et al.

Filed:

: November 12, 1999

Group Art Unit: 1635

Examiner:

: Epps, J.

For:

: New Transfection Reagents

Docket No.

: 61-03

Customer No.

: 23713

RESUBMISSION OF COPIES OF REFERENCES PREVIOUSLY SUBMITTED IN INFORMATION DISCLOSURE STATEMENT FILED MARCH 9, 2000

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Enclosed are copies of references previously submitted in this case on March 9, 2000 (along with proper 1449 forms) in an Information Disclosure Statement. U.S. patents listed on the 1449 forms have not been resubmitted. This submission results from a telephone request by Examiner Davies. Also enclosed is a copy of the returned post card date-stamped by the Patent Office indicating that the Information Disclosure Statement with 51 references was received on March 9, 2000.

Respectfully submitted,

GREENLEE, WINNER and SULLIVAN, P.C. 5370 Manhattan Circle, Suite 201, Boulder, CO 80303 Telephone (303) 499-8080; Fax (303) 499-8089

email: ssullivan@greenwin.com

Attorney docket no. 61-03

SAS:lem:2/25/05

Due Date:

Applicants: Chu et al.

Art Unit: To be assigned

Examiner:

To be assigned

Application No.:

09/438,365

Docket:

0942.4650001

Filed:

November 12, 1999

Atty:

RWE/THN

For:

New Transfection Reagents

-When receipt stamp is placed hereon, the USPTO acknowledges receipt of the following documents

1. PTO Transmittal Letter (in duplicate);

2. Information Disclosure Statement (in duplicate);

3. Form PTO-1449 (5 sheets citing 51 documents); and

4. 51 documents cited in Form PTO-1449.

MAR 0 9 2000 E

Please Date Stamp And Return To Our Courier

MDC

Sterne, Kessler, Goldstein & Fox P.L.L.C. 1100 New York Avenue, NW Washington, DC 20005-3934



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ANOREA J. KAMAGE**
NANCY J. LEITH**
TARJA H. NAUKKARINEN**

*BAR OTHER THAN D.C.
**REGISTERED PATENT AGENTS

March 9, 2000

WRITER'S DIRECT NUMBER: (202) 371-2560 INTERNET ADDRESS: RESMOND@SKGF.COM

Assistant Commissioner for Patents Washington, D.C. 20231

Re:

U.S. UtilityPatent Appl. No. 09/438,365; Filed: November 12, 1999

For: New Transfection Reagents

Inventors:

Chu et al.

Our Ref:

0942.4650001/RWE/THN

Sir:

Applicants submit the following documents for appropriate action by the U.S. Patent and Trademark Office:

- 1. Information Disclosure Statement (in duplicate);
- 2. Form PTO-1449 (5 sheets citing 51 documents);
- 3. 51 documents cited in Form PTO-1449; and
- 4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Assistant Commissioner for Patents March 9, 2000 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge all requisite fees to our Deposit Account No. 19-0036. A duplicate copy of this letter is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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Enclosures